

What is an immunotherapy?

Immunotherapy is a type of cancer treatment that stimulates the body's natural defenses (i.e. the immune system) to combat cancer. It works by re-educating the immune system to recognize cancer cells as abnormal and attack them, including the possibility of being able to control micrometastasis. The ultimate goal of immunotherapy is to facilitate tumor cells death, slowing tumor progression and/or allowing for mediating increased survival times. Immunotherapy may not be appropriate for all patients and all tumor types.

What is Torigen Autologous Prescription Product?

Torigen Autologous Prescription Product is a personalized cancer immunotherapy for the veterinary market. This new approach is tailored to each patient, and is made from the patient's tumor. Utilization of a whole tumor technique allows for inclusion of patient specific tumor-associated antigens, as well as stromal tissue-associated antigens. Cells from the surgically excised tumor are deactivated and combined with a natural particulate biomaterial to boost the immune system's response to the tumor tissue.

Who can administer Torigen Autologous Prescription Product?

Torigen Autologous Prescription Product is available by prescription to licensed veterinarians in the United States only.

How does Torigen Autologous Prescription Product work?

Torigen Autologous Prescription Product is posited to use the power of the body's own immune system to attack cancer by activating cytotoxic CD8+ T-cells, which target a combination of tumor antigens specific to that patient.

What is Torigen Autologous Prescription Product made from?

Torigen Autologous Prescription Product is made from the patient's tumor. The tumor tissue needs to be fresh or frozen. The vaccine is composed of deactivated tumor cells and a natural particulate biomaterial which may boost the immune system's response to the residual or metastatic tumor cells.

How much does Torigen Autologous Prescription Product cost?

Torigen Autologous Prescription Product typically costs significantly less than traditional cancer treatment (e.g. chemotherapy and radiation). We request that the veterinarian reach out to learn more today on how to offer this cost-effective approach in their clinic.

Is Torigen Autologous Prescription Product covered by insurance?

Yes, Torigen Autologous Prescription Product is covered by insurance as long as it is prescribed by a veterinarian.

What types of tumors can be treated with Torigen Autologous Prescription Product?

All tumors have foreign surface antigens that are potential targets for immunotherapy. Most solid tumors can be treated with Torigen Autologous Prescription Product. Please reach out if you have additional questions regarding tumor type.

What is the process for using Torigen Autologous Prescription Product?

After requesting a tumor collection kit, a patient presents to your clinic with a mass. Depending on signalment and presentation, confirmation of malignancy might be confirmed with fine needle aspiration (FNA) or biopsy and staging can be completed. The option of immunotherapy can be discussed with the client prior to surgery. The tumor is surgically excised with the intent of obtaining clean margins or reducing tumor burden from macroscopic to microscopic. The fresh or frozen excised tumor (**not** formalin-fixed) is sent to Torigen with the prepaid shipping materials. Upon arrival at Torigen's laboratory, the tumor is sectioned with appropriate tissue being submitted for histopathological diagnosis and margin evaluation, concurrently tumor and stromal tissues are selected for immunotherapy production. Vaccine development can begin immediately once a definitive diagnosis is received by Torigen. Vaccine development consists of reducing the tumor and stromal tissue to a single cell suspension, glutaraldehyde fixation, washing steps and combination with natural particulate biomaterial. The vaccine is sent to the attending veterinarian, and administration consists of one subcutaneous injection per week for 3 weeks for dogs and cats, or for 6 weeks for horses.

Torigen provides support during the complete diagnostic and treatment process. Obtaining short and long term treatment results is critical for Torigen in efforts to improve cancer care. Clinics utilizing Torigen Autologous Prescription Product will be asked to provide contact information to facilitate data gathering.

Where should Torigen Autologous Prescription Product be administered?

Torigen Autologous Prescription Product should be administered subcutaneously.

How much tumor tissue is required?

Ideally, the entire fresh or frozen tumor (**not** formalin-fixed) should be sent directly to Torigen, which allows us to submit the most representative samples for histologic assessment and vaccine production. We offer contracted pathology services upon request to simplify the submission process. We can also provide larger tumor collection jars/bags upon request.

Less than 3-5 grams of tissue, or about the size of a grape, may not provide an adequate number of cells to produce a typical vaccine, and may not provide enough tissue for proper histologic assessment, if requested. If there are concerns about the amount of available tissue, please call Torigen prior to surgery.

Notice! For experimental use only.

Autologous Prescription Product, Code 95A7.50 (unlicensed) is a service provided by Torigen Pharmaceuticals, Inc. and is regulated by the USDA Center for Veterinary Biologics. Treatment is administered only to the stated animal. Efficacy and safety have not been established by the USDA.

Torigen Pharmaceuticals, Inc.

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How long does it take to make Torigen Autologous Prescription Product?

Depending on your pathology choice, receipt of the tumor to our laboratory to receipt of the vaccine to your clinic takes 3-5 business days.

How should Torigen Autologous Prescription Product be stored?

Torigen Autologous Prescription Product should be refrigerated after receipt.

Is Torigen Autologous Prescription Product safe?

These claims have not been evaluated by the USDA Center for Veterinary Biologics; safety has not been established. In 2019, Torigen published a peer-reviewed manuscript entitled "Safety Evaluation of Autologous Tissue Vaccine Cancer Immunotherapy in a Canine Model" in *Anticancer Research*.¹ Within this publication, side-effects were observed and scored using an accepted clinical adverse event scoring system (VCOG-CTCAE). The results demonstrated that a low number (12%) of patients experienced limited, mild pyrexia, injection site swelling, or lethargy, all resolving without clinical intervention. These side effects are consistent with the responses observed with traditional vaccines. Please see Torigen's most recent publication on safety in cats for more information.²

Is Torigen Autologous Prescription Product effective?

These claims have not been evaluated by the USDA Center for Veterinary Biologics; efficacy has not been established. In 2020, Torigen published a peer-reviewed manuscript entitled "Evaluation of an autologous cancer vaccine for the treatment of metastatic canine hemangiosarcoma: a preliminary study" in *BMC Veterinary Research*.³ Within this publication, it was demonstrated that the overall median survival time for dogs treated with Torigen Autologous Prescription Product was survival similar to dogs treated with maximum-tolerated dose chemotherapy without any observed adverse events. Additional preliminary efficacy data sets, including anal sac adenocarcinoma and high-grade mast cell tumors are currently being evaluated for peer-review. For more information, please contact us to discuss further.

How fast does Torigen Autologous Prescription Product work?

If Torigen Autologous Prescription Product is being used as the sole method of treatment and the patient's immune system is capable of normal function, it can result in the generation of an immune system response that builds with successive doses during the 3 week treatment schedule. Patients that have been treated with prednisone or chemotherapy within 3 weeks of Torigen Autologous Prescription Product administration will likely have an altered immune response.

¹ Crossley, R. A., Matz, A., Dew, T., Kalinauskas, A., Faucette, N., Poff, B., ... Suckow, M. A. (2019). Safety Evaluation of Autologous Tissue Vaccine Cancer Immunotherapy in a Canine Model. *Anticancer Research*, 39 (4), 1699-1703. doi: 10.21873/anticancer.13275

² Lucroy MD, Kugler AM, El-Tayyeb F, Clauson RM, Kalinauskas AE, Suckow MA. Field safety experience with an autologous cancer vaccine in tumor-bearing cats: a retrospective study of 117 cases (2015-2020). *Journal of Feline Medicine and Surgery*. July 2021. doi:10.1177/1098612X211031504

³ Lucroy, M.D., Clauson, R.M., Suckow, M.A. et al. Evaluation of an autologous cancer vaccine for the treatment of metastatic canine hemangiosarcoma: a preliminary study. *BMC Vet Res* 16, 447 (2020). <https://doi.org/10.1186/s12917-020-02675-y>

Can Torigen Autologous Prescription Product be used in conjunction with chemotherapy and/or radiation?

Yes, Torigen Autologous Prescription Product can be used in conjunction with chemotherapy and/or radiation. For more information, please reach out to discuss these treatment protocols with one of our board-certified veterinary specialists in surgery and oncology.

What species can be given Torigen Autologous Prescription Product?

The Torigen Autologous Prescription Product is intended for companion animals. Dogs, cats, horses and exotic animals, such as ferrets have been treated to date.

What makes Torigen Autologous Prescription Product different from traditional cancer treatments?

Torigen Autologous Prescription Product utilizes the patient's own immune system to combat cancer. This treatment is often well tolerated by the patient, avoiding the adverse events often associated with chemotherapy or radiation. The administration of Torigen Autologous Prescription Product is completed in 3 short office visits, similar to yearly vaccines. In addition, it is significantly less expensive than traditional cancer treatment, such as chemotherapy or radiation therapy.

How can I learn more?

As a team of cancer researchers and veterinarians, we would love to tell you more about our personalized cancer immunotherapy, Torigen Autologous Prescription Product, and how you can offer it at your clinic today. Give us a call at **(860) 519-9956** or email **info@torigen.com** for more information.

In addition, we have board-certified veterinary specialists in oncology on our team who are available to discuss how to implement this product in your clinic, and to answer any case management questions you may have. Schedule a consultation with them today!

How do I get a free tumor collection kit?

Veterinarians can request a free tumor collection kit via: our website **www.torigen.com** email **info@torigen.com** over-the-phone **(860) 519-9956**.

The kit contains three insulated shipping containers for tumor submission with prepaid UPS labels. The kit can be kept on the shelf until you have a case you think would be a good candidate.

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